

State of Iowa
Board of Pharmacy

400 S.W. Eighth Street, Suite E, Des Moines, IA 50309-4688

<https://pharmacy.iowa.gov/>

Telephone: (515)281-5944 Facsimile: (515)281-4609

BOARD MEMBERS

LADONNA GRATIAS
EDWARD McKENNA
EDWARD MAIER

JAMES MILLER

Board Chair

ANDREW FUNK

Executive Director

BOARD MEMBERS

JASON HANSEL
SHARON MEYER

MINUTES

March 7-8, 2017

The Iowa Board of Pharmacy met on March 7-8, 2017, in the conference room at 400 SW Eighth Street, Des Moines, Iowa.

TUESDAY, MARCH 7, 2017

MEMBERS PRESENT

Sharon K. Meyer, Vice-Chair
LaDonna Gratias
Jason Hansel
Edward L. Maier
Edward J. McKenna

MEMBERS ABSENT

James Miller, Chairperson

STAFF PRESENT

Andrew Funk, Executive Director
Meghan Gavin, Esq., Assistant Attorney General
Therese Witkowski, Executive Officer
Jennifer Tiffany, Associate Director - PMP
Becky Hall, Secretary
Curt Gerhold, Compliance Officer
Mark Mather, Compliance Officer
Sue Mears, Compliance Officer
Jennifer O'Toole, Compliance Officer
Jean Rhodes, Compliance Officer
Daniel Sedlacek, Compliance Officer
James Wolfe, Compliance Officer

Call to Order & Announcements

At 9:05 a.m., Sharon Meyer, Vice-Chair called the meeting of the Iowa Board of Pharmacy to order on Tuesday, March 7, 2017.

Administrative Hearings

2016-133, Taylor Paul, Pharmacy Technician Registration No. 3339, Indianola.

At 9:06 a.m., Laura Lockard, Administrative Law Judge, Department of Inspections and Appeals opened the record. Assistant Attorney General Meghan Gavin represented the State. Ms. Paul did not appear nor did counsel represent her. The session was conducted in the presence of the Board and closed to the public.

At 9:17 a.m., motion by Jason Hansel, seconded by LaDonna Gratias, the Board voted unanimously by roll call vote to move into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case.

At 9:47 a.m., while still in closed session, LaDonna Gratias moved that the Board go into open session, seconded by Edward McKenna. Motion approved unanimously.

Motion by LaDonna Gratias, seconded by Edward McKenna, to direct Administrative Law Judge Lockard to draft the Order consistent with the Board's deliberations in case 2016-133, Taylor Paul. Motion approved unanimously.

Annual Performance Evaluation of Executive Director

At 9:48 a.m., on a motion by Jason Hansel, seconded by Edward Maier, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa Code Section 21.5(1)(i), to evaluate the professional competency of an individual whose appointment, hiring, performance, or discharge is being considered when necessary to prevent needless and irreparable injury to that individual's reputation and that individual requests a closed session.

At 10:40 a.m., while still in closed session, Jason Hansel, moved that the Board go into open session, seconded by Edward Maier. Motion approved unanimously.

Motion by Jason Hansel, seconded by Edward Maier, to approve what was discussed in closed session. Motion approved unanimously.

Closed Session

At 10:52 a.m., on a motion by Jason Hansel, seconded by Edward McKenna, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa Code Section 21.5(1)(a), to review or discuss records which are required or authorized by state or federal law to be kept confidential; pursuant to Iowa Code Section 21.5(1)(d), to discuss whether to initiate licensee disciplinary investigations or proceedings; and pursuant to Iowa Code Section 21.5(1)(f), to discuss the decision to be rendered in a contested case conducted according to the provisions of Chapter 17A.

At 12:03 p.m., while still in closed session, Jason Hansel moved that the Board go into open session, seconded by LaDonna Gratias. Motion approved unanimously.

Closed Session

At 12:50 p.m., on a motion by Jason Hansel, seconded by LaDonna Gratias, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa Code Section 21.5(1)(a), to review or discuss records which are required or authorized by state or federal law to be kept confidential; and pursuant to Iowa Code Section 21.5(1)(d), to discuss whether to initiate licensee disciplinary investigations or proceedings conducted according to the provisions of Chapter 17A.

At 3:35 p.m., while still in closed session Jason Hansel moved that the Board go into open session, seconded by Edward Maier. Motion approved unanimously.

In open session the following actions were taken:

1. Closed Session Minutes and Deliberations.

Motion by Edward McKenna, seconded by Jason Hansel, to approve the Closed Session Deliberations of the January 4, 2017, meeting and Closed Session Minutes of the January 4-5, 2017, meeting. Motion approved unanimously.

2. Close With No Further Action.

Motion by Edward McKenna, seconded by LaDonna Gratias, to close with no further action the following investigative files in complaint numbers: 2013-81, 2013-129, 2013-201, 2016-125, 2016-142, 2016-106, 2016-135, 2016-181, 2017-4, 2016-178, 2016-145, 2016-164, 2016-128, 2016-182, and 2016-191. Motion approved unanimously.

3. Close With No Further Action.

Motion by Edward Maier, seconded by Jason Hansel, to close with no further action case 2016-154. Sharon Meyer abstained. Motion passed.

4. Close With No Further Action.

Motion by Edward Maier, seconded by Edward McKenna, to close with no further action case 2016-186. Jason Hansel abstained. Motion passed.

5. Draft Statement of Charges.

Motion by Edward McKenna, seconded by LaDonna Gratias, to draft Statement of Charges against the pharmacy in 2017-35; pharmacy in 2016-144; pharmacist in 2016-187; and pharmacy and pharmacist in charge in 2016-193. Motion approved unanimously.

6. Notice of Hearing and Statement of Charges.

Motion by Edward McKenna, seconded by Jason Hansel, to approve the Notice of Hearing and Statement of Charges adding citation to Count IV in case 2016-43, Charles A. Robinson. Motion approved unanimously. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum A.

7. Settlement Agreement and Final Order.

Motion by Jason Hansel, seconded by Edward McKenna, to approve the Settlement Agreement and Final Order in the following cases. Motion approved unanimously.

A. 2015-81, Remedies, Inc., Pharmacy License No. 611, Sibley. A copy of the Settlement Agreement and Final Order is attached as Addendum B.

B. 2015-81, Alan Hoppe, Pharmacist License No. 18117, Sibley. A copy of the Settlement Agreement and Final Order is attached as Addendum C.

C. 2016-78, Pacifico National Inc., d/b/a Amex Pharmacy, Nonresident Pharmacy License No. 3942, Melbourne, Florida. A copy of the Settlement Agreement and Final Order is attached as Addendum D.

D. 2016-150, Rajan Devan, Pharmacist License No. 19480, West Des Moines. A copy of the Settlement Agreement and Final Order is attached as Addendum E.

8. Combined Statement of Charges, Settlement Agreement, and Final Order.

Motion by Edward McKenna, seconded by Jason Hansel, to approve the Combined Statement of Charges, Settlement Agreement, and Final Order in case 2016-154, Victor Van Cleave, Pharmacy Technician Registration No. 18662, Des Moines. Sharon Meyer abstained. Motion passed. A copy of the Combined Statement of Charges, Settlement Agreement, and Final Order is attached as Addendum F.

9. Combined Statement of Charges, Settlement Agreement, and Final Order.

Motion by Edward McKenna, seconded by Jason Hansel, to approve the Combined Statement of Charges, Settlement Agreement, and Final Order in case 2017-8, Karen Jean Gaulrapp, Pharmacy Technician Registration No. 5901, Coal Valley, Illinois. Motion approved unanimously. A copy of the Combined Statement of Charges, Settlement Agreement, and Final Order is attached as Addendum G.

10. Close With No Further Action.

Motion by Edward McKenna, seconded by LaDonna Gratias, to close with no further action the following investigative files in complaint numbers: 2016-192, and 2017-5. Motion approved unanimously.

11. Administrative Warning.

Motion by Edward McKenna, seconded by Jason Hansel, to issue an Administrative Warning to the pharmacy in 2016-174; and pharmacy, pharmacist in charge, and pharmacist in 2017-7. Motion approved unanimously.

At 3:40 p.m. the Board recessed.

The meeting reconvened in open session on Wednesday, March 8, 2017, at 9:00 a.m.

WEDNESDAY, MARCH 8, 2017

MEMBERS PRESENT

Sharon K. Meyer, Vice-Chair
LaDonna Gratias
Jason Hansel
Edward L. Maier
Edward J. McKenna

MEMBERS ABSENT

James Miller, Chairperson

SPEAKERS

Kate Gainer, IPA
Anthony Pudlo, IPA
Jim Mennen, Hy-Vee
Megan Myers, IPA

STAFF PRESENT

Andrew Funk, Executive Director
Meghan Gavin, Esq., Assistant Attorney General
Laura Steffensmeier, Esq., Assistant Attorney General
Therese Witkowski, Executive Officer
Jennifer Tiffany, Associate Director - PMP
Becky Hall, Secretary
Curt Gerhold, Compliance Officer
Mark Mather, Compliance Officer
Sue Mears, Compliance Officer
Jennifer O'Toole, Compliance Officer
Jean Rhodes, Compliance Officer
Daniel Sedlacek, Compliance Officer
Jim Wolfe, Compliance Officer

Michael Andreski, Drake
Brett Barker, NuCara
Ashley Loeffelholz, NuCara
Brenda Foust, UnityPoint

Call to Order and Announcements

At 9:02 a.m., Sharon Meyer, Vice-Chair, called the meeting of the Iowa Board of Pharmacy to order on Wednesday, March 8, 2017.

Public Comments

Edward Maier and James Miller will complete their final terms as members of the Board on April 30, 2017. Kate Gainer with the Iowa Pharmacy Association (IPA) expressed thanks on behalf of IPA and the pharmacy profession for their service.

Edward Maier expressed his gratitude to IPA, Board members, other constituents, and acknowledged James Miller for the opportunity to have worked with them.

Sharon Meyer and Andrew Funk expressed appreciation on behalf of the Board and board staff for their leadership and service as Board members.

Approval of Minutes

The minutes of the January 4-5, 2017, meeting were reviewed.

Motion by Edward Maier, seconded by LaDonna Gratiyas, to approve the open session minutes of the January 4-5, 2017, meeting as presented. Motion approved unanimously.

Reports

1. Executive Director's Report -

Office/Program Updates

A. Vacant Compliance Officer Position.

Paperwork requesting the filling of the vacant Compliance Officer position will occur within the coming weeks.

B. Administrative Assistant 2 Position.

Amanda Woltz will be joining the Iowa Board of Pharmacy staff as an Administrative Assistant 2. Ms. Woltz will begin her position on March 24, 2017

C. Database Update.

The Request for Proposal (RFP) for a new database has been published. The closing date of the RFP has been extended to March 17, 2017, at the request of three separate vendors. The Department of Administrative Services (DAS) has approved the request. An estimated implementation date for the new database is scheduled for July 1, 2017, with a estimated Go Live date scheduled for January 15, 2018.

D. Request for Proposal for Upgraded Prescription Monitoring Program (PMP) Software.

The Office of the Chief Information Officer (OCIO) has given the board staff authorization to proceed with developing a RFP for upgraded PMP software. The Iowa Department of Public Health recently filed a grant request and included the Iowa Board of Pharmacy's PMP program. Board staff should be notified by May 1, 2017, if the grant has been awarded.

E. Pharmacy Technician Certification Board (PTCB).

The Pharmacy Technician Certification Board indefinitely postponed its 2020 initiative that would have required technicians to have completed an ACPE-accredited educational program in order to sit for the examination. PTCB recently held a Stakeholder's Consensus Meeting in Dallas, Texas, and results of the meeting have not yet been published.

F. Office Remodel.

The office remodel plans for the Iowa Board of Pharmacy have been approved by Director Funk. Director Funk is waiting for final approval from the Iowa Dental Board as some of the office space will be merged with them. Construction of the remodel is estimated to begin in May or June of 2017.

G. APPE Internship Program.

The board office will begin accepting P3-P4 students from Drake and the University of Iowa Colleges of Pharmacy, hosting two students from Drake and three students from the University of Iowa throughout the remainder of 2017. Sue Mears, Jennifer Tiffany, Jennifer O'Toole, and Andrew Funk will serve as the student's preceptors.

H. Secret Shopper.

The Board requested to have the Compliance Officers review options for verifying adherence to counseling and appropriateness of therapy rules through the development of a secret shopper program. The project will begin in April, 2017.

I. Board Member Appointments.

LaDonna Gratias has been reappointed for her third and final term. Gayle Mayer, Spirit Lake; Brett Barker, Nevada; and Joan Skogstrom, Urbandale have been appointed by the Governor's office and will begin their terms on May 1, 2017.

Meetings and Travel

A. The Multistate Pharmacy Jurisprudence Examination (MPJE) Item Development Workshop will be held March 14-16, 2017, in Northbrook, Illinois. Jennifer O'Toole and Andrew Funk plan to attend.

B. The APhA Annual Meeting will be held March 24-27, 2017, in San Francisco, California.

C. The National Rx Drug Abuse and Heroin Summit will be held on April 17-19, 2017, in Atlanta, Georgia. Andrew Funk and Jennifer Tiffany plan to attend.

D. The May board meeting is scheduled for May 9-10, 2017, in Des Moines, at the board office.

- E. The National Association of Boards of Pharmacy's (NABP) 113th Annual Meeting will be held on May 20-23, 2017, in Orlando, Florida. Edward McKenna, Jason Hansel, and Andrew Funk plan to attend.
 - F. The ASHP Summer Meeting will be held June 3-7, 2017, in Minneapolis, Minnesota.
 - G. The Iowa Pharmacy Association Annual Meeting will be held June 16-17, 2017, in Coralville.
 - H. The June board meeting is scheduled for June 27-28, 2017, in Des Moines, at the board office.
 - I. The Iowa Board of Pharmacy will be hosting the 2017 NABP/AACP District 5 Annual Meeting. The meeting will be held on August 3-5, 2017.
2. Legislative Update – Meghan Gavin.
- A. Study Bill 1074 is the Board of Pharmacy's bill amending Iowa Code 155A. This bill is still alive and has made it through the first funnel deadline.
 - B. Senate File 332 is the Annual Controlled Rescheduling bill to conform to federal drug schedules. This bill is still alive and has made it through the first funnel deadline.
 - C. House Files 198 and 199 - There has been discussion about expanding the current decriminalization of the possession of marijuana derivative product cannabidiol. There are no provisions in the current program for the manufacture or distribution of CBD within the state of Iowa. Provisions to expand the program are no longer alive and failed to pass through funnel. In the original bill the program was scheduled to sunset the summer of 2017, provisions to extend the deadline of the program have passed through funnel.
- Additional information provided by Sue Mears – House File 520 is still active in the House Chamber and is eligible for debate, but has been amended to incorporate language from House Study Bill 132 and House File 199 to allow for manufacture and distribution in Iowa.
- D. House Study Bills 138 and 174 - There are various bills regarding changing Iowa's licensing process, deregulating certain boards, moving certain licensing to various departments throughout the State as opposed to having a Board made up of practitioners. Those bills did not affect the Board of Pharmacy.
 - E. Study Bill 173 is a bill regarding telepharmacy to put more specific requirements into statute that the Board of Pharmacy has been considering in rules. The bill appears not to have made it through funnel and may be addressed by Leadership at a later date.
 - F. House Files 523 and 532 – There are various Iowa Prescription Monitoring Program (PMP) bills, including one proposed by the Board of Pharmacy regarding changes to the PMP. A couple of the bills are still alive. Current drafts include when a practitioner registers with the Board for a CSA registration they would be automatically registered for the PMP.
3. Iowa Prescription Monitoring Program 2016 Report.

The Iowa PMP is administered by the Board with the assistance and guidance of an advisory council consisting of pharmacists and prescribers appointed by the Governor. Terry Witkowski provided a summary of the report.

4. Iowa Monitoring Program for Pharmacy Professionals (IMP3) Report.

Jennifer O'Toole provided a summary of the report.

5. Drug Take Back Quarterly Reports

A. Iowa's Medication Disposal Program for Non-Controlled Substances Quarterly Report for October – December, 2016.

IPA provided their Quarterly report for Iowa's Medication Disposal Program for Non-Controlled Substances for review.

B. Iowa Pharmaceutical Collection and Disposal - Drug Enforcement Administration (DEA) Compliant Collection Receptacles Quarterly Progress Report for October – December, 2016; and January – March, 2017.

Jennifer Tiffany provided a summary of the report.

6. Hy-Vee Pharmacy Fulfillment Center's 2016 Quarter Four Error Report.

Hy-Vee Pharmacy Fulfillment Center submitted their 2016 Quarter Four Error Report for review.

7. NuCara's 2016 Quarter Four Telepharmacy Report.

NuCara submitted their 2016 Quarter Four Telepharmacy Report for review.

8. New Practice Model for Community Pharmacy - Phase Three, Quarter Two Report and Phase Four, Quarter One Report – Megan Myers, IPA.

IPA provided their Phase Three, Quarter Two Report; and Phase Four, Quarter One Report for the New Practice Model for Community Pharmacy. Megan Myers and Michael Andreski provided a summary of the report.

9. Mercy Family Pharmacy, Dyersville – Phase Four, Quarter Two Report – New Practice Model for Community Pharmacy – Julie Panosh, Dyersville.

Mercy Family Pharmacy submitted their Phase Four, Quarter Two Report for the New Practice Model for Community Pharmacy for review.

10. Allen Hospital's 2017 Tech-Check-Tech Quarter Four Report.

Allen Hospital submitted their 2017 Quarter Four Tech-Check-Tech Report for review.

11. Dangerous Drug Interaction – Illinois

Informational item.

12. Food and Drug Administration (FDA) Guidance for Industry-Biosimilars/NCSL Report.

Informational item.

Requests

1. Request for Waiver – 657 I.A.C. 6.16 Records – Hy-Vee Pharmacy Clinic 1504, Bloomfield.

Motion by Edward Maier, seconded by Jason Hansel, to approve the request for waiver for five years. Motion approved unanimously.

2. Request for Waiver – 657 I.A.C. 8.15(155A) Delivery of Prescription Drugs and Devices and 8.15(2) Policies and Procedures Required – NuCara #28, Ashley Loeffelholz.

Motion by Edward Maier, seconded by LaDonna Gratias, to approve as a variance once initiated, with the conditions quarterly reports are submitted for two years and a copy of the pharmacy's Policy and Procedures is provided. Motion approved unanimously.

3. Request for Approval of Tech-Check-Tech Program for UnityPoint Health Finley Hospital, Dubuque – Brenda Foust.

Motion by Jason Hansel, seconded by Edward Maier, to approve the request. Sharon Meyer abstained. Motion passed.

Closed Session

At 10:37 a.m., motion by Jason Hansel, seconded by Edward Maier, the Board voted unanimously by roll call vote to move into closed session for the following reason.

For requests pursuant to Iowa Code Section 21.5(1)(a), to review or discuss records which are required or authorized by state or federal law to be kept confidential under Iowa Code Section 272C.6 and 22.7(2).

At 10:44 a.m., while still in closed session, Edward Maier moved that the Board go into open session, seconded by Jason Hansel. Motion approved unanimously.

Motion by Edward Maier, seconded by LaDonna Gratias, to approve what was discussed in closed session. Motion approved unanimously.

Request

Request for Early Release From Probation – Kimberly Robertson, Pharmacist License No. 15845, Des Moines.

Motion by Edward Maier, seconded by Jason Hansel, to deny the request. Motion approved unanimously.

Licensure/Registrations

Heather Jacobs, Davenport – new Iowa Controlled Substances Act Registration Application.

Motion by Jason Hansel, seconded by Edward Maier, to approve the new Iowa Controlled Substances Act Registration Application. Motion approved unanimously.

Requests

1. Senate File 282 - An Act Relating to the Medical Use of Cannabidiol.

Motion by Edward Maier, seconded by Edward McKenna the Board's position is neutral. Motion approved unanimously.

2. Request for Internship Hours Credit – Olufunmilayo George-Taylor, Burlington.

Motion by Edward McKenna, seconded by LaDonna Gratias, to grant 500 hours of internship for life experience requiring Ms. George-Taylor to obtain an additional 1,000 hours of internship. Motion approved unanimously.

Rules

Notice of Intended Action – Amend Chapter 8, “Universal Practice Standards,” and Adopt new Chapter 13, “Telepharmacy Practice.”

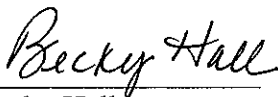
Motion by Jason Hansel, seconded by Edward Maier, to approve for filing Notice of Intended Action. Motion approved unanimously. A copy of the Notice of Intended Action is attached as Addendum H.

Complaints Against Non-Licensees


2016-99, Patient Support Group (www.thepatientsupportgroup.com.)

Motion by Edward Maier, seconded by Jason Hansel to close and refer to the Iowa Board of Nursing, Iowa Board of Medicine, and Iowa Board of Physician Assistants. Motion approved unanimously.

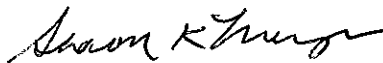
Motion by Edward Maier, seconded by Jason Hansel, to adjourn at 11:30 a.m. on March 8, 2017.



Becky Hall
Recording Secretary



Andrew Funk
Executive Director



Sharon K. Meyer
Vice-Chair

APPROVED THIS 10th DAY OF May, 2017.

ADDENDUM A

**NOTICE OF HEARING
AND
STATEMENT OF CHARGES**

**CHARLES ALAN ROBINSON
PHARMACIST LICENSE NO. 13371
ESTHERVILLE, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2016-43
Pharmacist License of)	
)	
CHARLES ALAN ROBINSON)	NOTICE OF HEARING AND
License No. 13371)	STATEMENT OF CHARGES
Respondent.)	

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Charles Robinson pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)(e), and 657 Iowa Administrative Code rules 35.5 and 36.5. Respondent's Iowa pharmacist license number 13371 is currently active through June 30, 2017.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on May 9, 2017, before the Board. The hearing shall begin at 9 a.m. and shall be located in the Board conference room located at the Iowa Board of Pharmacy Office, 400 S.W. 8th Street, Suite E, Des Moines, Iowa, 50309-4688.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 Iowa Administrative Code rule 35.11. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

Filing of Pleadings. Pleadings shall be filed with the Board at the following address: Iowa Board of Pharmacy, 400 S.W. 8th Street, Suite E, Des Moines, Iowa, 50309-4688.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the Board at hearing.

Pre-hearing Conference. Any party may request a prehearing conference in accordance with 657 Iowa Administrative Code rule 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 Iowa Administrative Code chapter 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 Iowa Administrative Code rule 35.16. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The Office of Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of pleadings should be provided to counsel for the State at the following address:

Meghan Gavin
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor, Hoover State Office Building
Des Moines, Iowa 50319

Ms. Gavin can also be reached by phone at (515) 281-6736 or by e-mail at Meghan.Gavin@iowa.gov.

Communications. You may contact the Board office at (515) 281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the opportunity to participate, such as at the hearing or in pleadings you file with the Board office and serve upon all parties in the case.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2015).

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 147, 155A, and 272C, and 657 Iowa Administrative Code chapter 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 Iowa Administrative Code rule 35.21.

C. CHARGES

COUNT I

FAILURE TO PROPERLY VERIFY AND DOCUMENT

Respondent is charged with failing to provide, document, and retain a record of the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to delivery to the patient in violation of Iowa Code sections 147.55(9) and 155A.12(1), and 657 Iowa Administrative Code rules 8.3(4)(c), 8.3(7), 8.19(2), 10.21(2), (5), and 36.1(4)(u), (ap).

COUNT II

VIOLATION OF THE DUTIES OF THE PHARMACIST-IN-CHARGE

Respondent is charged with violating the duties of the pharmacist-in-charge in violation of Iowa Code section 147.55(9) and 155A.12(1), and 657 Iowa Administrative Code rules 8.3(4)(a), (c), (i), (j), 8.3(5)(c), and 36.1(4)(u).

COUNT III

FAILURE TO PERFORM A DRUG UTILIZATION REVIEW

Respondent is charged with failing to perform a drug utilization review in violation of Iowa Code section 147.55(9) and 155A.12(4) and 657 Iowa Administrative Code rules 8.21 and 36.1(4)(u).

COUNT IV

DISPENSING A SCHEDULE II CONTROLLED SUBSTANCE WITHOUT A PRESCRIPTION

Respondent is charged with dispensing a schedule II controlled substance without a signed prescription in violation of Iowa Code section 147.55(9) and 155A.12(1) and 657 Iowa Administrative Code rules 8.19(3), 10.21(2), (5), and 36.1(4)(u).

D. FACTUAL CIRCUMSTANCES

1. Respondent is the pharmacist-in-charge and owner of Estherville Drug.
2. Estherville Drug provides pharmacy services to some residents and intermittent pharmacy services to the residents of Good Samaritan.
3. The Director of Nursing at Good Samaritan called in a prescription for Patient 1 to Estherville Drug for fentanyl 12.5 mcg/hr transdermal patches—a Schedule II Controlled Substance.
4. Respondent requested that the Director of Nursing verify the strength as fentanyl patches are not made in a 12.5 mcg/hr strength. The Director incorrectly “verified” the drug strength as fentanyl 125 mcg/hr.
5. Respondent did not contact the authorizing physician.
6. Respondent performed a drug utilization review using only the limited drug history in the pharmacy’s system despite Patient 1 not being a regular patient of the pharmacy.
7. Respondent dispensed the prescription prior to receiving the signed, hard-copy prescription.

8. Patient 1 was transported to the local emergency department thirty-six hours after the fentanyl patch was administered. Patient 1 developed pneumonia and kidney failure and ultimately expired.

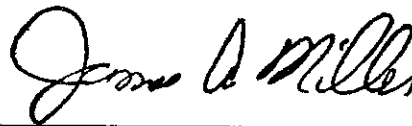
9. Respondent did not complete a Continuous Quality Improvement incident report.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 Iowa Administrative Code rule 36.6. If you are interested in pursuing settlement in this matter, please contact Assistant Attorney General Meghan Gavin at (515) 281-6736.

F. FINDING OF PROBABLE CAUSE

On this March day of 7, 2017, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



Chairperson
Iowa Board of Pharmacy

Copy to:

Meghan Gavin
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).

ADDENDUM B

**SETTLEMENT AGREEMENT
AND
FINAL ORDER**

**REMEDIES, INC.
PHARMACY LICENSE NO. 611
SIBLEY, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-81
Pharmacy License of)	
)	SETTLEMENT AGREEMENT
REMEDIES, INC.)	AND FINAL ORDER
License No. 611)	
Respondent.)	

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 Iowa Administrative Code rule 36.6, the Iowa Board of Pharmacy and Remedies, Inc. ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case currently pending before the Board.

The allegations contained in the Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. The Board filed a Notice of Hearing and Statement of Charges on November 4, 2015.
2. The Respondent pharmacy is now closed. This Agreement along with the Agreement in the companion case, *In re: the Pharmacist License of Alan Hoppe*, resolves the matter currently pending before the Board.
3. The Board has jurisdiction over the parties and the subject matter of these proceedings.
4. Respondent has chosen not to contest the allegations in the Notice of Hearings and Statement of Charges, but acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Agreement.
5. Execution of this Agreement constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
6. Respondent acknowledges that it has the right to be represented by counsel on this matter, and is indeed represented by attorney Craig Sieverding.
7. Respondent agrees that the State's counsel may present this Agreement to the Board and may have *ex parte* communications with the Board while presenting it.
8. This Agreement is subject to approval by a majority of the full Board. If the Board does not approve this Agreement, it shall be of no force or effect to either party, and shall not be

admissible for any purpose in further proceedings in this matter. If the Board approves this Agreement, it shall be the full and final resolution of this matter.

9. This Agreement shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

10. This Agreement shall not be binding as to any new complaints received by the Board.

11. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

12. This Agreement, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.


13. The Board's approval of this Agreement shall constitute a FINAL ORDER of the Board.

IT IS THEREFORE ORDERED:

14. Respondent is CITED for engaging in unethical conduct and dispensing a Schedule II Controlled Substance subject to a facsimile and WARNED that violating the laws and rules governing the practice of pharmacy could result in further discipline.

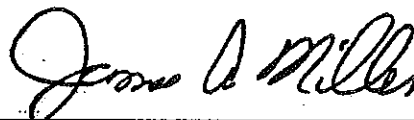
15. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 1st day of March, 2017.


Remedies, Inc.
Respondent

By this signature, Alan B. Hoppo acknowledges s/he is the Owner / PIC for Remedies, Inc. and is authorized to sign this Settlement Agreement and Final Order on behalf of Remedies, Inc.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 7th day of March, 2017.



Chairperson
Iowa Board of Pharmacy

Copies to:

Meghan Gavin
Assistant Attorney General
Licensing & Administrative Law Division
Iowa Department of Justice
Hoover Building, 2nd Floor
Des Moines, IA 50319
ATTORNEY FOR THE STATE

Craig Sieverding
Davis Brown
215 10th Street, Suite 1300
Des Moines, IA 50309
ATTORNEY FOR RESPONDENT

ADDENDUM C

SETTLEMENT AGREEMENT
AND
FINAL ORDER

ALAN HOPPE
PHARMACIST LICENSE NO. 18117
SIBLEY, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-81
Pharmacist License of)	
)	
ALAN HOPPE)	SETTLEMENT AGREEMENT
License No.18117)	AND FINAL ORDER
Respondent.)	

COME NOW the Iowa Board of Pharmacy and Alan Hoppe ("Respondent") and enter into this Settlement Agreement and Final Order ("Order") pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 Iowa Administrative Code rule 36.6, to settle a license disciplinary proceeding currently pending before the Board.

The allegations contained in the Statement of Charges against the Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent holds Iowa pharmacist license 18117, which is currently active.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. The Board issued a Statement of Charges concerning Respondent's pharmacist license on November 4, 2015.
4. Respondent has chosen not to contest the charges, but acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
5. Execution of this Settlement Agreement and Final Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Agreement. This Agreement shall constitute the final order of the Board in this case and shall have the force and effect of a disciplinary order entered following a contested case hearing.
6. Respondent is freely and voluntarily entering into this Agreement. Respondent further agrees that the State's counsel may present this Agreement to the Board and may have *ex parte* communications with the Board while presenting it.

7. This Agreement shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

8. This Agreement is subject to approval by the Board. If the Board does not approve this Agreement, it shall be of no force or effect on either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Agreement, it shall be the full and final resolution of this matter.

9. This Agreement, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

10. Respondent acknowledges that he has a right to be represented by counsel in these proceedings, and indeed is represented by attorney Craig Sieverding.

11. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

12. This Agreement shall not be binding as to any new complaints received by the Board.

13. The Board's approval of this Agreement shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

1. Respondent's license to practice pharmacy in the State of Iowa is hereby **SUSPENDED** effective immediately.

2. Respondent may not request reinstatement of his license for at least six months from Board approval of this Agreement. Respondent may request reinstatement of his Iowa pharmacist license by filing an application for reinstatement under 657 Iowa Administrative Code rule 36.13. Respondent's license shall not be reinstated except upon a showing by the Respondent that the basis for suspension of his license no longer exists, and that it is in the public interest for the license to be reinstated.

3. Respondent agrees not to work in a pharmacy in any capacity in Iowa unless and until his pharmacist license is reinstated. Upon reinstatement, Respondent's license shall be placed on **PROBATION** for three years.

4. Respondent shall pay a **CIVIL PENALTY** in the amount of five thousand dollars (\$5000) within sixty (60) days of Board approval of this Agreement. The check shall be made payable to

the "Treasurer of Iowa" and shall be deposited in the general fund. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Jennifer O'Toole, 4000 SW Eighth Street, Suite E, Des Moines, IA 50309.

5. Respondent shall have no involvement, directly or indirectly, in the ownership, management, direction, or control of any business engaged in the practice of the pharmacy. Respondent may not request release from this prohibition for a period of five years.

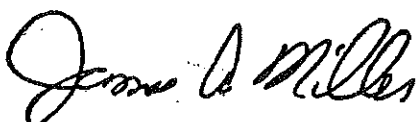
6. Respondent shall not serve as a pharmacist-in-charge. Respondent may not request release from this prohibition for a period of five years.

7. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 Iowa Administrative Code chapter 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 1st day of March, 2017.


ALAN HOPPE
Respondent

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 3rd day of March, 2017.


Chairperson
Iowa Board of Pharmacy

Copy to:

Meghan L. Gavin
Assistant Attorney General
Licensing & Administrative Law Division
Iowa Department of Justice

Hoover Building, 2nd Floor
Des Moines, IA 50319
ATTORNEY FOR THE STATE

Craig Sieverding
Davis Brown
215 10th Street, Suite 1300
Des Moines, IA 50309
ATTORNEY FOR RESPONDENT

ADDENDUM D

SETTLEMENT AGREEMENT
AND
FINAL ORDER

PACIFICO NATIONAL INC.
d/b/a AMEX PHARMACY
NONRESIDENT PHARMACY LICENSE NO. 3942
MELBOURNE, FLORIDA

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2016-78
Nonresident Pharmacy License of)	
)	
PACIFICO NATIONAL INC.)	SETTLEMENT AGREEMENT
d/b/a AMEX PHARMACY)	AND FINAL ORDER
License No. 3942)	
Respondent.)	

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and Pacifico National Inc. d/b/a Amex Pharmacy ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case currently pending before the Board.

The allegations contained in the Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. The Board filed a Notice of Hearing and Statement of Charges on November 1, 2016.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. Respondent acknowledges that the allegations in the Statement of Charges, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
5. Respondent acknowledges that it has the right to be represented by counsel on this matter.
6. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

8. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

9. This Order shall not be binding as to any new complaints received by the Board.

10. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

11. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

12. The Board's approval of this Order shall constitute a FINAL ORDER of the Board.

IT IS THEREFORE ORDERED:

13. Respondent is hereby **CITED** for failing to timely notify the Board of discipline imposed by another licensing authority and **WARNED** that Respondent's failure to comply with the laws and rules governing the practice of pharmacy in the future could result in further discipline.

14. Respondent's license is hereby placed on **PROBATION** for one (1) year or the entirety of Respondent's probationary period in Florida, whichever is longer. Respondent shall comply with all terms of the Florida settlement agreement. In addition, the following probationary terms shall apply:

- a. Within thirty (30) days, Respondent shall submit a copy of the written corrective action plan required by the Florida settlement agreement to the Board.
- b. Within thirty (30) days of any inspections conducted at the facility by any licensing authority or regulatory body, including the Florida Department of Health and the FDA, Respondent shall submit a notification to the Board describing the scope of the inspection, any deficiencies identified, and any corrective actions taken.
- c. Respondent shall notify the Board within ten (10) days of any changes regarding the status of its Florida pharmacy permit.
- d. Respondent shall appear before the Board upon request for the purpose of reviewing the facility's performance during the probationary period. Respondent shall be given reasonable notice of the date, time, and place for such appearances.
- e. Respondent shall obey all laws and rules governing the practice of pharmacy.

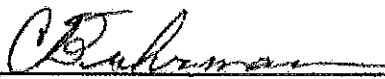
- f. The notifications required to be submitted to the Board pursuant to this paragraph should be mailed to the Iowa Board of Pharmacy, Attn: Jennifer O'Toole, 400 SW Eighth Street, Suite E, Des Moines, IA 50309, or emailed to Jennifer.OToole@iowa.gov.

15. Respondent shall pay a **CIVIL PENALTY** in the amount of five-thousand dollars (\$5000) within thirty (30) days of Board approval of this Order. The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Jennifer O'Toole, 400 SW Eighth Street, Suite E, Des Moines, IA 50309.

16. Respondent is hereby permitted to withdraw its Iowa Wholesale Drug License Application because Respondent can continue to be licensed as an Iowa nonresident pharmacy until the Board implements licensure for outsourcing facilities.

17. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC 36.

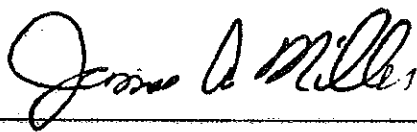
This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 23 day of February, 2017.



PACIFICO NATIONAL INC.
d/b/a AMEX PHARMACY
Respondent

By this signature, Christina Behrman acknowledges s/he is the Pharmacist In Charge for Pacifico National Inc. d/b/a Amex Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Pacifico National Inc. d/b/a Amex Pharmacy.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 7th day of March, 2017.



Chairperson
Iowa Board of Pharmacy

Copies to:

**Laura Steffensmeier
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE**

**Michael Sellers
Sellers, Galenbeck & Nelson
An Association of Sole Practitioners
400 Locust Street, Suite 170
Des Moines, IA 50309-2351
ATTORNEY FOR RESPONDENT**

ADDENDUM E

SETTLEMENT AGREEMENT
AND
FINAL ORDER

RAJAN DEVAN
PHARMACIST LICENSE NO. 19490
WEST DES MOINES, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2016-150
Pharmacist License of)	
)	
RAJAN DEVAN)	SETTLEMENT AGREEMENT
License No.19490)	AND FINAL ORDER
Respondent.)	

COME NOW the Iowa Board of Pharmacy and Rajan Devan ("Respondent") and enter into this Settlement Agreement and Final Order ("Order") pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 Iowa Administrative Code rule 36.6, to settle a license disciplinary proceeding currently pending before the Board.

The allegations contained in the Statement of Charges against the Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent holds Iowa pharmacist license 19490, which is currently active.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. The Board issued a Statement of Charges concerning Respondent's pharmacist license on January 4, 2017.
4. With the exception of Count IV, Respondent has chosen not to contest the charges, but acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
5. Should Respondent violate the terms of this Settlement Agreement and Final Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A and Iowa Administrative Code chapter 657—36.
6. Execution of this Settlement Agreement and Final Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Agreement. This Agreement shall constitute the final order of the Board in this case and shall have the force and effect of a disciplinary order entered following a contested case hearing.

7. Respondent is freely and voluntarily entering into this Agreement. Respondent further agrees that the State's counsel may present this Agreement to the Board and may have *ex parte* communications with the Board while presenting it.

8. This Agreement shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

9. This Agreement is subject to approval by the Board. If the Board does not approve this Agreement, it shall be of no force or effect on either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Agreement, it shall be the full and final resolution of this matter.

10. This Agreement, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

11. Respondent acknowledges that he has a right to be represented by counsel in these proceedings and indeed is represented by attorney Thomas Crabb.

12. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

13. This Agreement shall not be binding as to any new complaints received by the Board.

14. The Board's approval of this Agreement shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

1. Count IV, Failing to Maintain an Accurate Perpetual Inventory is hereby DISMISSED.

2. Respondent's license to practice pharmacy in the State of Iowa is hereby SUSPENDED effective immediately.

3. Respondent may not request reinstatement for at least one year from the date of this Order. Respondent may request reinstatement of his Iowa pharmacist license by filing an application for reinstatement under 657 Iowa Administrative Code rule 36.13. Respondent's license shall not be reinstated except upon a showing by Respondent that the basis for

revocation of his license no longer exists, and that it is in the public interest for the license to be reinstated.


4. Respondent agrees not to work in a pharmacy in any capacity in Iowa unless and until his pharmacist license is reinstated.

5. Respondent shall have no involvement, directly or indirectly, in the ownership, management, direction, or control of any business engaged in the practice of the pharmacy without the express, written consent of the Board.

6. Respondent shall not serve as a pharmacist-in-charge without the express, written consent of the Board.

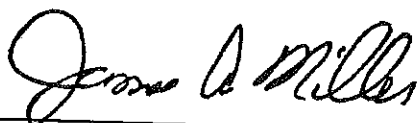
7. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 Iowa Administrative Code chapter 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 24 day of February, 2017.



RAJAN DEVAN
Respondent

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 7th day of March, 2017.



Chairperson
Iowa Board of Pharmacy

Copy to:

Meghan L. Gavin
Assistant Attorney General

Licensing & Administrative Law Division
Iowa Department of Justice
Hoover Building, 2nd Floor
Des Moines, IA 50319
ATTORNEY FOR THE STATE

Thomas G. Crabb
418 6th Ave. Ste. 200
Des Moines, IA 50309
ATTORNEY FOR RESPONDENT

ADDENDUM F

**COMBINED STATEMENT OF
CHARGES, SETTLEMENT AGREEMENT,
AND FINAL ORDER**

**VICTOR VAN CLEAVE
PHARMACY TECHNCIAN REGISTRATION NO. 18662
DES MOINES, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2016-154
Certified Technician Registration of)	
)	
VICTOR VAN CLEAVE)	COMBINED STATEMENT OF
Registration No. 18662)	CHARGES, SETTLEMENT
Respondent.)	AGREEMENT, AND FINAL ORDER

COME NOW the Iowa Board of Pharmacy ("Board") and Victor Van Cleave ("Respondent"), and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Order") pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2015), and 657 IAC 36.6. The Board has jurisdiction over Respondent and the subject matter of these cases pursuant to Iowa Code chapters 17A, 147, 155A, and 272C, and 657 IAC chapter 36.

A. STATEMENT OF CHARGES

COUNT I

DIVERTING PRESCRIPTION DRUGS

1. Respondent is charged with diverting prescription drugs from a pharmacy for personal use or for distribution, pursuant to Iowa Code sections 147.55(9) and 155A.6A(5), and 657 IAC 36.1(4)"ak".

COUNT II

CONTRIBUTING TO THE DISPENSING OF AN INCORRECT PRESCRIPTION

2. Respondent is charged with dispensing, or contributing to the dispensing of, and incorrect prescription, pursuant to Iowa Code sections 147.55(9) and 155A.6A(5), and 657 IAC 36.1(4)"ap".

B. FACTUAL CIRCUMSTANCES

3. From August to October of 2016, Respondent diverted approximately 252 vials of Fentanyl and 18 vials of hydromorphone from the Omnicell cabinets at his place of employment.

4. Respondent replaced the diverted liquid with sterile water, which resulted in patients not receiving pain medication.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

5. The Board has jurisdiction over the parties and the subject matter of these proceedings.

6. Respondent admits the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case hearing, would constitute grounds for the

discipline agreed to in this Order.

7. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

8. Respondent acknowledges that he has the right to be represented by counsel on this matter.

9. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

10. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

11. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

12. This Order shall not be binding as to any new complaints received by the Board.

13. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

14. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

15. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

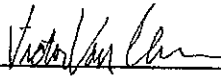
IT IS THEREFORE ORDERED:

16. Respondent agrees to **VOLUNTARILY SURRENDER** his pharmacy technician registration to resolve this matter. This voluntary surrender is considered discipline and, when accepted by the Board, has the same force and effect as an order of revocation under 657 IAC 36.15. Respondent is permanently barred from applying for reinstatement under 657 IAC 36.13.

17. Respondent agrees not to work in a pharmacy in any capacity in Iowa.

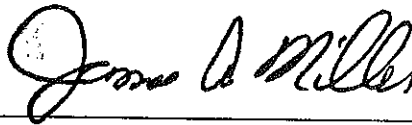
18. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC 36.

This Combined Statement of Charges, Settlement Agreement, and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the ____ day of October, 2016.



VICTOR VAN CLEAVE
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on the 7th day of ~~November, 2016~~
March, 2017.



Chairperson
Iowa Board of Pharmacy

ADDENDUM G

**COMBINED STATEMENT OF
CHARGES, SETTLEMENT AGREEMENT,
AND FINAL ORDER**

**KAREN JEAN GAULRAPP
PHARMACY TECHNCIAN REGISTRATION NO. 5901
COAL VALLEY, ILLINOIS**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2017-8
Certified Technician Registration of)	
)	
KAREN JEAN GAULRAPP)	COMBINED STATEMENT OF
Registration No. 5901)	CHARGES, SETTLEMENT
Respondent.)	AGREEMENT, AND FINAL ORDER

COME NOW the Iowa Board of Pharmacy ("Board") and Karen Jean Gaulrapp ("Respondent"), and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Order") pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2016), and 657 IAC 36.6. The Board has jurisdiction over Respondent and the subject matter of these cases pursuant to Iowa Code chapters 17A, 147, 155A, and 272C, and 657 IAC chapter 36.

A. STATEMENT OF CHARGES

COUNT I

UNETHICAL BEHAVIOR—THEFT

1. Respondent is charged with engaging in unethical behavior, specifically theft, in violation of 657 IAC 3.28(4), pursuant to Iowa Code sections 147.55(3) and 155A.6A(5), and 657 IAC 3.30, 36.1(4)"c" and 36.1(4)"u".

B. FACTUAL CIRCUMSTANCES

2. Respondent's certified technician registration number 5901 is currently active through February 28, 2018.

3. From approximately July 2015 through January 2017, Respondent admitted to taking money from her employer.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

4. The Board has jurisdiction over the parties and the subject matter of these proceedings.

5. Respondent admits the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case hearing, would constitute grounds for the discipline agreed to in this Order.

6. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Order. Once entered, this Order shall have

the force and effect of a disciplinary order entered following a contested case hearing.

7. Respondent acknowledges that she has the right to be represented by counsel on this matter.

8. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

9. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

10. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

11. This Order shall not be binding as to any new complaints received by the Board.

12. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

13. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

14. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.


IT IS THEREFORE ORDERED:

15. Respondent agrees to **VOLUNTARILY SURRENDER** her pharmacy technician registration to resolve this matter. This voluntary surrender is considered discipline and, when accepted by the Board, has the same force and effect as an order of revocation under 657 IAC 36.15.

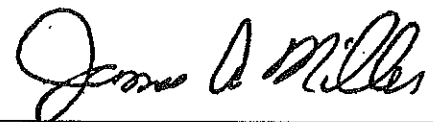
16. Respondent agrees not to work in a pharmacy in any capacity in Iowa unless her certified pharmacy technician registration is reinstated. Respondent may not request reinstatement for at least five (5) years from the date of this Order.

17. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC chapter 36.

This Combined Statement of Charges, Settlement Agreement, and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 23 day of February, 2017.


KAREN JEAN GAULRAPP
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on the 7th day of March, 2017.


Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE

ADDENDUM H

NOTICE OF INTENDED ACTION

**CHAPTER 8, "UNIVERSAL PRACTICE STANDARDS,"
AND ADOPT NEW
CHAPTER 13, "TELEPHARMACY PRACTICE"**

MARCH 8, 2017

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 8, "Universal Practice Standards," and to adopt new Chapter 13, "Telepharmacy Practice," Iowa Administrative Code.

The amendments were approved at the March 8, 2017, regular meeting of the Board of Pharmacy.

The proposed amendment to subrule 8.35(2) identifies a telepharmacy practice as a defined subset of a limited use pharmacy license type. The proposed rules in new Chapter 13 provide standards for the provision of pharmaceutical services to patients through the use of audio-visual technologies that link the telepharmacy site with a managing pharmacy, allowing a verifying pharmacist at the remote pharmacy to oversee and verify the dispensing processes performed by the technician at the telepharmacy site. The audio-visual technology also ensures that the patient and the pharmacist are able to converse, face-to-face over secure connections, about the patient's drug treatment plan.

The proposed rules define terms used in the chapter and assign responsibilities for various aspects of the practices involved. The proposed rules require a written agreement between the managing pharmacy and the telepharmacy site, identifying specific required provisions and contents of the written agreement and what must occur in case the agreement is terminated or either pharmacy closes. The proposed rules identify the general requirements for a telepharmacy site, a managing pharmacy, a verifying pharmacist, and a telepharmacy technician, including addressing specific training and experience requirements for those personnel.

The required information to be provided with the initial application for a limited use

pharmacy license as a telepharmacy site and the minimum information to be provided in a request for waiver of the minimum distance between a proposed telepharmacy site and an existing pharmacy that dispenses prescription drugs to outpatients are identified. Specific application and notification requirements in the case of a change of telepharmacy site or managing pharmacy name, location, ownership, or pharmacist in charge are identified. The proposed rules provide that the opening of a new pharmacy within 10 miles of an existing telepharmacy site does not force the closing of the telepharmacy site.

Subjects to be addressed by policies and procedures to be adopted and implemented by both the telepharmacy site and the managing pharmacy are listed and information and reports required of a telepharmacy site or managing pharmacy are identified. The proposed rules identify specific records that must be maintained by and available at a telepharmacy site including the monthly inspection of the telepharmacy site by a pharmacist from the managing pharmacy.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34. Requirements for waiver of the specific restrictions regarding location of a telepharmacy site within 10 miles of another pharmacy that dispenses prescription drugs to outpatients are identified in subrule 13.16(8).

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on May 16, 2017. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by email to terry.witkowski@iowa.gov.

A public hearing was held on August 30, 2016, during a regularly held meeting of the Board. Numerous written and oral comments, objections, and suggestions were received both by persons

attending the hearing and other interested persons. The results of additional discussions between Board staff, legislators, the Governor's staff, and industry were shared with the Board. The Board considered all of these comments and suggestions when composing these rules.

After analysis and review of this rulemaking, the Board has been unable to determine whether the adoption of these rules will have an impact on jobs or the net result of any possible impact. The establishment of telepharmacy sites where a pharmacy currently does not exist may create jobs for pharmacy technicians and also for verifying pharmacists. However, the establishment of a telepharmacy site in place of an existing pharmacy that intends to close, as a means of preserving the availability of pharmacy services in a community or area, may still result in the overall reduction in the number of jobs in that area.

These rules are intended to implement Iowa Code sections 124.301, 147.107, 155A.3, 155A.6A, 155A.13, 155A.14, 155A.19, 155A.28, 155A.31, 155A.33, and 155A.41.

The following amendments are proposed.

Item 1. Amend subrule 8.35(2) as follows:

8.35(2) Limited use pharmacy license. Limited use pharmacy license may be issued for nuclear pharmacy practice, correctional facility pharmacy practice, telepharmacy practice, and veterinary pharmacy practice. Applications for limited use pharmacy license for these and other limited use practice settings shall be determined on a case-by-case basis.

Item 2. Adopt new 657—Chapter 13, Telepharmacy Practice, as follows:

Chapter 13

Telepharmacy Practice

657—13.1(155A) Purpose and scope. The purpose of this chapter is to provide standards for the

provision of telepharmacy services to patients. These rules provide for pharmaceutical care services at a telepharmacy site utilizing audio-visual technologies that link the telepharmacy site with a managing pharmacy and one or more verifying pharmacists. The telepharmacy site and the managing pharmacy shall be located within Iowa and shall maintain appropriate licensure by the board.

657—13.2(155A) Definitions. For purposes of this chapter, the following definitions shall apply.

“Board” means the board of pharmacy.

“CSA” or *“CSA registration”* means a registration issued pursuant to Iowa Code section 124.303 and 657—Chapter 10.

“DEA” means the Drug Enforcement Administration of the U. S. Department of Justice.

“Managing pharmacy” means a licensed pharmacy located in Iowa that oversees the activities of one or more telepharmacy sites.

“Telepharmacy” means the practice of pharmacy where pharmaceutical care services are provided using audio-visual technologies linking a telepharmacy site with the managing pharmacy.

“Telepharmacy site” means a licensed pharmacy that is operated by a managing pharmacy and staffed by one or more telepharmacy technicians where pharmaceutical care services, including the storage and dispensing of prescription drugs, drug utilization review, and patient counseling, are provided by a licensed pharmacist through the use of technology.

“Verifying pharmacist” means a remote Iowa-licensed pharmacist or pharmacists who perform any step in the prescription verification and dispensing process including but not limited to: verification of data entry; product selection, packaging, and labeling; drug utilization review;

and patient counseling.

657—13.3(124,155A) Written agreement. The managing pharmacy and the telepharmacy site shall execute and maintain a current written agreement between the pharmacies. If there is no current written agreement between the pharmacies, the telepharmacy site shall immediately notify the board and shall discontinue operations as a telepharmacy site until a current written agreement between the managing pharmacy and the telepharmacy site is executed.

13.3(1) Contents of agreement. The written agreement between the managing pharmacy and a telepharmacy site shall include, but may not be limited to, the following:

a. Staffing, to include telepharmacy technician staffing, verifying pharmacist staffing and availability, and on-site pharmacist staffing as needed.

b. Hours of operation of the telepharmacy site and hours of availability of pharmacists at the managing pharmacy.

c. Emergency contact information for the managing pharmacy and the telepharmacy site.

d. Complete description of the audio-visual technology to be utilized to link the managing pharmacy and the telepharmacy site.

e. A provision that, in the event that the telepharmacy technician is not available at the telepharmacy site, that a verifying pharmacist is not available, or that the audio-visual communication connection between the telepharmacy site and the managing pharmacy is not available, the telepharmacy site shall close pending the availability of the technician, the verifying pharmacist, and the communication link or pending the arrival at the telepharmacy site of a pharmacist to provide onsite pharmacy services.

f. Activities and services to be provided by the managing pharmacy at the telepharmacy site.

g. Identification of contact persons to receive, on behalf of the managing pharmacy and the telepharmacy site, notifications and official communications regarding the written agreement. Identification of contact persons shall include delivery addresses and preferred methods of delivery of the written communications required by this rule and any other communications affecting the written agreement between the managing pharmacy and the telepharmacy.

h. Pharmacy locations, other than the managing pharmacy, where verifying pharmacists may be based or located.

13.3(2) Termination of agreement. A managing pharmacy shall provide written notice to the Board and to the telepharmacy site 90 days in advance of the managing pharmacy's intent to terminate the agreement between the telepharmacy site and the managing pharmacy. A telepharmacy site shall provide written notice to the Board and to the managing pharmacy 90 days in advance of the telepharmacy site's intent to terminate the agreement between the managing pharmacy and the telepharmacy site.

a. New agreement. A new written agreement between a managing pharmacy and the telepharmacy site, including the filing of a new pharmacy license application identifying the new pharmacist in charge, shall be executed within the 90-day advance notification period.

b. No new agreement. If the telepharmacy site is unable to contract with a new managing pharmacy, the telepharmacy site shall, 30 days prior to the expiration of the 90-day advance notification period, implement the prior notification requirements for closing a telepharmacy site as provided in subrule 13.3(3). The telepharmacy site shall cease operations and close at the end of that 30-day closing notification period unless a new written agreement is executed.

13.3(3) Closing of telepharmacy site. A telepharmacy site that intends to close the

telepharmacy site shall provide written notification to the managing pharmacy and the board as provided in 13.3(2). In addition, the telepharmacy site shall provide written notification to the DEA and to patients and shall comply with all requirements for closing a pharmacy as provided in subrule 657—8.35(7).

13.3(4) Closing of managing pharmacy. A managing pharmacy that intends to close the managing pharmacy shall provide written notification to the telepharmacy site and the board as provided in 13.3(2). In addition, the managing pharmacy shall provide written notification to the DEA and to patients and shall comply with all requirements for closing a pharmacy as provided in subrule 657—8.35(7). A telepharmacy site that has been managed by the closing pharmacy shall comply with the provisions of subrules 13.3(2) and 13.3(3), as applicable.

657—13.4(155A) Responsible parties. The responsibilities identified and assigned pursuant to rule 657—8.3(155A) shall be assigned, as appropriate, to the managing pharmacy and the telepharmacy site, by and through their respective owners or license holders, to the pharmacist in charge and to staff pharmacists, including verifying pharmacists. A telepharmacy technician shall share responsibility with the pharmacist in charge, the telepharmacy site, and the verifying pharmacist, as assigned in rule 657—8.3(155A), for all functions assigned to and performed by the telepharmacy technician.

657—13.5 to 13.7 Reserved.

657—13.8(124,155A) General requirements for telepharmacy site. The telepharmacy site shall maintain a pharmacy license issued by the board. If the telepharmacy site plans to dispense controlled substances, the telepharmacy site shall also maintain a CSA registration and a DEA registration.

13.8(1) Located in Iowa. A telepharmacy site shall be located within the state of Iowa.

13.8(2) Pharmacist in charge. The pharmacist in charge of the telepharmacy site shall be the pharmacist in charge of the managing pharmacy.

13.8(3) Security. A telepharmacy site shall employ methods to prevent unauthorized access to prescription drugs, devices, and pharmacy and patient records. Such methods may include an alarm system and shall include other security systems and methods as provided by these rules. Alarm systems and entry system locks should be disarmed when the telepharmacy site is staffed and open for business. Minimum security methods shall include:

a. Electronic keypad or other electronic entry system into the telepharmacy site or the pharmacy department that requires and records the unique identification of the individual accessing the pharmacy, including the date and time of access. Complete access records shall be maintained for a minimum two years beyond the date of access.

b. Secure storage such as a safe.

c. Controlled access to computer records.

d. A continuous system of video surveillance and recording of the pharmacy department that includes maintenance of recordings for a minimum 60 days following the date of the recording.

13.8(4) Telepharmacy site signage. In addition to the patient counseling sign required pursuant to subrule 13.8(5), one or more signs, prominently posted in every prescription pick-up area and clearly visible to the public, shall inform the public that the location is a telepharmacy site supervised by a pharmacist at a remote location. Signage shall include the name, location, and telephone number of the managing pharmacy. The telepharmacy site shall also prominently post the days and times that the telepharmacy is open for business.

13.8(5) Patient counseling. Patient counseling as required by rule 657—6.14(155A) shall be provided utilizing the audio-visual technology employed between the telepharmacy site and the managing pharmacy. Every telepharmacy site shall post in every prescription pickup area, in a manner clearly visible to patients, a notice that Iowa law requires the pharmacist to discuss with the patient any new prescriptions dispensed to the patient. The board shall provide a telepharmacy site with the required signage.

13.8(6) Label requirements. In addition to the label requirements identified in subrule 657—6.10(1), the label affixed to or on the dispensing container of any prescription drug or device dispensed by a telepharmacy site pursuant to a prescription drug order shall include, on the primary label or affixed by use of an auxiliary label, the following:

- a. The name, telephone number, and address of the telepharmacy site;
- b. The name and telephone number of the managing pharmacy.

13.8(7) Prohibited activities. In the physical absence of a pharmacist, the following activities are prohibited:

- a. Practice of pharmacist-interns or pharmacy support persons at the telepharmacy site.
- b. Advising patients regarding OTC products unless that advice is communicated directly by a pharmacist to the patient.
- c. Dispensing or delivering prescription medications packaged by a technician into patient med paks unless an onsite pharmacist has verified the drugs in the patient med paks.
- d. Tech-check-tech practice.
- e. Compounding, unless an onsite pharmacist has verified the accuracy and completeness of the compounded drug product.

f. All judgmental activities identified in rule 657—3.23(155A) that a pharmacy technician is prohibited from performing in the practice of pharmacy.

13.8(8) Continuous quality improvement. A telepharmacy site shall implement and participate in a continuous quality improvement program pursuant to rule 657—8.26(155A).

13.8(9) Technology failure. If the audio-visual technology between the telepharmacy site and the managing pharmacy or the verifying pharmacist is not operational, no prescriptions shall be dispensed from the telepharmacy site to a patient unless a pharmacist is physically present at the telepharmacy site.

13.8(10) Perpetual controlled substances inventory. A telepharmacy site that dispenses controlled substances shall maintain a perpetual inventory record of those controlled substances.

a. The perpetual inventory record requirement shall apply to all controlled substances maintained and dispensed by the telepharmacy site and shall not be limited only to Schedule II controlled substances.

b. The perpetual inventory record format and other requirements provided in rule 657—10.33(124,155A) shall apply to the telepharmacy site's perpetual inventory record of controlled substances, with the following exceptions:

(1) The perpetual inventory record shall contain records for all controlled substances, not just Schedule II controlled substances, and

(2) Audit of the perpetual inventory record shall be completed and the physical and perpetual inventories shall be reconciled pursuant to the requirements of subrule 10.33(4) each month as part of the inspection of the telepharmacy site.

657—13.9(155A) General requirements for managing pharmacy.

13.9(1) Distance to telepharmacy site. The managing pharmacy shall be located in Iowa and within a 200-mile radius of a telepharmacy site, to ensure that the telepharmacy site is sufficiently supported by the managing pharmacy and that necessary personnel or supplies may be delivered to the telepharmacy site within a reasonable period of time of an identified need.

13.9(2) Emergency preparedness plan. A managing pharmacy shall develop and include in both the managing pharmacy's and the telepharmacy site's policies and procedures a plan for continuation of pharmaceutical services provided by the telepharmacy site in case of an emergency interruption of the telepharmacy site's services. The plan shall address the timely arrival at the telepharmacy site of necessary personnel or the delivery to the telepharmacy site of necessary supplies within a reasonable period of the identification of an emergency need. The plan may provide for alternate methods of continuation of the services of the telepharmacy site including, but not limited to, personal delivery of patient prescription medications from an alternate pharmacy location or onsite pharmacist staffing at the telepharmacy site.

13.9(3) Pharmacist in charge. The pharmacist in charge of the managing pharmacy shall be the pharmacist in charge of the telepharmacy site.

13.9(4) Adequate audio-visual connection. The pharmacist in charge shall ensure adequate audio-visual connection with the telepharmacy site during all periods when the telepharmacy site is open for business including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

13.9(5) Monthly inspection. The pharmacist in charge or delegate pharmacist shall be responsible for performing a monthly inspection of the telepharmacy site. Inspection reports shall be signed by the individual pharmacist who performed the inspection. Inspection records

and reports shall be maintained at the telepharmacy site for two years following the date of the inspection. A copy of the inspection report shall be provided to and maintained at the managing pharmacy. The monthly inspection shall include, but may not be limited to, the following:

- a.** Audit and reconciliation of controlled substances perpetual and physical inventories;
- b.** Audit of electronic entry system and records;
- c.** Verification that the video recording system is functioning properly and that the recordings are maintained and available for at least 60 days past the date of the recording;
- d.** Compilation of a record of the number of prescriptions filled, the number of onsite pharmacist hours, and the number of hours the pharmacy site was open for business during the preceding month.
- e.** Review of written policies and procedures and verification of compliance with those policies and procedures;
- f.** Ensuring compliance with and review of records in the continuous quality improvement program, following up with responsible personnel to address issues identified by incident reports to prevent future incidents;
- g.** Review of records of the receipt and disbursement of prescription drugs, including controlled substances, to ensure compliance with recordkeeping requirements;
- h.** Inspection of drug supplies and storage areas to ensure removal and quarantine of outdated drugs;
- i.** Inspection of stock drug supplies and storage areas to ensure drugs are maintained in a manner to prevent diversion and maintain the integrity of the drugs, verifying that the temperatures of storage areas are appropriate for the stored drugs and equipment,

j. Inspection of pharmacy and storage areas and shelves to ensure areas and shelves are clean and free of pests and other contaminants.

13.9(6) Onsite pharmacist staffing. In an effort to promote public health, the telepharmacy site shall be staffed by a pharmacist for at least 16 hours per month. While on site, the pharmacist shall make available to the community general health care services which may include, but not necessarily be limited to, immunizations, medication therapy management, or health screenings, as deemed necessary and appropriate by the pharmacist in charge and as provided by policies and procedures.

a. If a pharmacist will be available at the telepharmacy site to provide in-person patient services, a consistent schedule of the pharmacist's availability shall be established and published.

b. Signage identifying the days and times when a pharmacist is onsite and available to patients shall be conspicuously posted at the telepharmacy site and may be published by other means, as deemed appropriate.

c. Notice that the pharmacist will not be present at the telepharmacy site during any routinely scheduled and posted onsite availability shall be provided to the public in advance of the absence except as provided in the emergency preparedness plan.

d. If the average number of prescriptions dispensed per day by the telepharmacy site exceeds 150 prescriptions, the telepharmacy site shall provide onsite pharmacist staffing 100% of the time the pharmacy is open for business and shall, within 10 business days, apply to the Board for licensure as a general pharmacy. The average number of prescriptions dispensed per day shall be determined by averaging the number of prescriptions dispensed per day over the previous 90-day period.

657—13.10(155A) General requirements for verifying pharmacist. A verifying pharmacist shall maintain a current and active license to practice pharmacy in Iowa.

13.10(1) Location of verifying pharmacist. The verifying pharmacist who is performing patient counseling shall be physically located within the managing pharmacy or another pharmacy licensed to operate a pharmacy in Iowa.

13.10(2) Adequate audio-visual connection. The verifying pharmacist shall ensure adequate audio-visual connection with the telepharmacy site during all periods when the pharmacist is responsible for verifying telepharmacy site activities and practices including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

13.10(3) Verifying pharmacist training. A verifying pharmacist shall be adequately trained on the use of the technology to ensure accurate verification and patient counseling and shall review and understand the policies and procedures of the managing pharmacy and the telepharmacy site.

13.10(4) Patient refusal of counseling. If a patient or patient's caregiver refuses patient counseling, the refusal shall be directly communicated by the patient or patient's caregiver to the pharmacist through audio-visual communication. A technician may not accept and communicate a refusal of patient counseling from the patient or patient's caregiver to the pharmacist.

13.10(5) Reference library. A verifying pharmacist shall have access to all required references applicable to the telepharmacy services provided at the telepharmacy site.

657—13.11(155A) General requirements for telepharmacy technician. A telepharmacy technician shall maintain current national certification and registration in good standing with the board as a certified pharmacy technician.

13.11(1) Practice experience. Before practicing in a telepharmacy site, a telepharmacy technician shall have completed a minimum of 2,000 hours of practice experience as a certified pharmacy technician, at least 1,000 hours of which shall be practicing in an Iowa-licensed pharmacy and 160 hours of which shall be practicing in a managing pharmacy.

13.11(2) Training. In addition to training required of all pharmacy technicians, a telepharmacy technician shall complete the following minimum training requirements before practicing in a telepharmacy site. Records of telepharmacy technician training shall be documented and maintained by the telepharmacy site.

- a. Review and understanding of the policies and procedures of the managing pharmacy.
- b. Review and understanding of the policies and procedures of the telepharmacy site.
- c. Review and understanding of these rules for telepharmacy practice.
- d. Review and understanding of pharmacy technician rules, 657 – Chapter 3.
- e. Understanding of the operation of the audio-visual technologies to be utilized at both pharmacies.
- f. Training at the telepharmacy site under the direct supervision of an onsite verifying pharmacist. Training shall include operation and use of the audio-visual technology and other means of communication between the telepharmacy site and the managing pharmacy and all daily operations from unlocking and opening the telepharmacy site to closing and locking the telepharmacy site at the end of the business day. If the telepharmacy site is protected by one or more alarm systems, training shall include how to disarm and engage the alarm system or systems.

13.11(3) Continuing education. Beginning with the first full two-year continuing education

period for renewal of the technician's national pharmacy technician certification after beginning practice as a telepharmacy technician, and for each subsequent renewal of national certification for as long as the technician continues to practice as a telepharmacy technician, the technician shall complete two hours of continuing education in each of the following activities. These continuing education requirements shall not be in addition to the total continuing education credits required to maintain national certification.

a. Patient safety/medication errors.

b. Pharmacy law.

13.11(4) Identification. The telepharmacy technician shall, at all times when the technician is practicing at the telepharmacy site and the telepharmacy site is open for business, wear a name badge or tag identifying the technician. The badge or tag shall include, at a minimum, the technician's first name and title. The name badge or tag shall be so designed and worn that the technician's name and title are clearly visible to the public at all times.

13.11(4) Adequate audio-visual connection. The telepharmacy technician shall ensure adequate audio-visual connection with the managing pharmacy during all periods when the telepharmacy site is open for business including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

657—13.12 to 13.15 Reserved.

657—13.16(124,155A) Telepharmacy site – initial application.

13.16(1) License application. A telepharmacy site shall complete and submit to the board a limited use/telepharmacy license application and fee as provided in rule 657—8.35(155A). In addition to the application and fee, the telepharmacy site shall include the additional information

identified in this rule.

13.16(2) CSA registration application. If controlled substances will be dispensed from the telepharmacy site, the telepharmacy site shall complete and submit, with the limited use/telepharmacy license application and fee, the CSA registration application and fee as provided in rule 657—10.1(124).

13.16(3) Identification of managing pharmacy. The telepharmacy site application shall include identification of the managing pharmacy including pharmacy name, license number, address, telephone number, pharmacist in charge, and a statement from the managing pharmacy or pharmacist in charge indicating that the managing pharmacy has executed a written agreement to provide the required services and oversight to the telepharmacy site.

13.16(4) Distance to nearest general pharmacy. The telepharmacy site application shall identify the nearest licensed pharmacy that dispenses prescription drugs to outpatients and shall provide evidence identifying the total driving distance between the proposed telepharmacy site and the nearest currently licensed general pharmacy.

a. If the distance between the proposed telepharmacy site and the nearest currently licensed general pharmacy is less than ten miles, the telepharmacy site shall submit a request for waiver of the distance requirement. The process and requirements for a request for waiver are identified in subrule 13.16(8).

b. The distance requirement shall not apply under any of the following circumstances:

(1) The telepharmacy site was approved by the board and operating as a telepharmacy site prior to July 1, 2016.

(2) The proposed telepharmacy site is located within a hospital campus and services will be

limited to inpatient dispensing.

(3) The proposed telepharmacy site is located on property owned, operated, or leased by the state.

13.16(5) Written agreement. The telepharmacy site application shall include the written agreement between the telepharmacy site and the managing pharmacy as described in subrule 13.3(1).

13.16(6) Key personnel. The telepharmacy site application shall identify key personnel including the pharmacist in charge of the managing pharmacy and the telepharmacy site and the telepharmacy technician or technicians at the telepharmacy site. Identification shall include the names, the license or registration numbers, and the titles of the key personnel. Telepharmacy technician identification shall also include a copy of the telepharmacy technician's current national certification or other verification of the telepharmacy technician's current national certification.

13.16(7) Audio-visual technology. A description of the audio-visual technology system to be used to link the managing pharmacy and the telepharmacy site, including built-in safeguards relating to verification of the accuracy of the dispensing processes. Safeguards shall include but may not be limited to:

a. Prior to authorizing the telepharmacy site's system to print a prescription label and prior to filling the prescription at the telepharmacy site, requiring a verifying pharmacist to review and compare the electronic image of any new prescription presented to the telepharmacy technician for filling with the data entry record of the prescription.

b. Requiring the technician to use barcode technology at the telepharmacy site to verify the

accuracy of the drug to be dispensed.

c. Requiring remote visual confirmation by a verifying pharmacist of the drug stock bottle and the drug to be dispensed prior to dispensing the prescription at the telepharmacy site.

d. Ensuring the telepharmacy site's system prevents a prescription from being sold and delivered to a patient prior to the verifying pharmacist performing a final verification of the accuracy of the prescription and releasing the prescription for sale and delivery at the telepharmacy site.

13.16(8) Request for distance waiver. The board shall consider a request for waiver of the distance requirement between the proposed telepharmacy site and the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients if the petitioner can demonstrate to the board that the proposed telepharmacy site is located in an area where there is limited access to pharmacy services and that there exist compelling circumstances that justify waiving the distance requirement.

a. The request for waiver shall be prepared and shall include the elements of a request for waiver or variance identified in 657 Chapter 34.

b. In addition to the requirements of 657 Chapter 34, the request for waiver shall include evidence and specific information regarding each of the following, if applicable. If an item identified below does not apply to the proposed telepharmacy site, the request for waiver shall specifically state that the item does not apply.

(1) That the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients is open for business for limited hours or fewer hours than the proposed telepharmacy site.

(2) That the proposed telepharmacy site intends to provide services not available from the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients.

(3) That access to the nearest currently licensed general pharmacy that dispenses prescription drugs to outpatients is limited and a description of how the proposed telepharmacy site will improve patient access to pharmacy services.

(4) That limited access to pharmacy services is affecting patient safety.

(5) That there are transportation barriers to services from the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients.

(6) That the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients is closing.

(7) That the proposed telepharmacy site is located in an area of the state where there is limited access to pharmacy services.

c. The board shall consider a request for waiver of the distance requirement during any open session of a meeting of the board. One or more representatives of the parties to the waiver request, including representatives of the proposed telepharmacy site, the managing pharmacy, and the nearest currently licensed general pharmacy, shall be invited and encouraged to attend the meeting at which the waiver request is scheduled for consideration to be available to respond to any questions.

d. The board's decision to grant or deny the request for waiver of the distance requirement shall be a proposed decision and shall be reviewed by the director of the department of public health.

(1) The director shall have the power to approve, modify, or veto the board's proposed

decision regarding the waiver request.

(2) The director's decision on a waiver request shall be considered final agency action.

(3) The director's decision (final agency action) shall be subject to judicial review under Iowa Code chapter 17A.

657—13.17(124,155A) Telepharmacy site or managing pharmacy changes. Except as specifically provided by these rules, a change to a telepharmacy site shall require compliance with the licensure and notification requirements of the specific type of change identified in 657 subrules 8.35(6) and 8.35(7). A change affecting the CSA registration shall comply with the appropriate requirements of rule 657—10.11(124).

13.17(1) Change of pharmacist in charge. A change of pharmacist in charge shall require submission of a pharmacy license application for the managing pharmacy and the telepharmacy site as provided by subrule 657—8.35(6).

13.17(2) Closing or selling pharmacy. A telepharmacy site or managing pharmacy that intends to close or sell the pharmacy practice shall comply with all requirements for closing or selling a pharmacy found at 657 subrules 8.35(6) and 8.35(7) regarding ownership change and closing a pharmacy, including all advance notification requirements. A purchaser of a telepharmacy site shall complete and submit applications and supporting information as provided in rule 657—13.16(124,155A). A closing pharmacy shall also comply with the requirements of subrule 13.3(3) or 13.3(4), as appropriate.

13.17(3) Location change. A telepharmacy site that intends to move to a new location that is outside the community wherein the telepharmacy site has been located, if the telepharmacy site intends to provide telepharmacy services from the new location, shall comply with the

requirements of subrule 13.17(2) for closing a pharmacy and shall submit applications and supporting information as provided in rule 657—13.16(124,155A). A managing pharmacy that intends to move to a new location shall comply with the requirements of 657 subrules 8.35(5), 8.35(6), and 8.35(7), as appropriate.

657—13.18(155A) Traditional pharmacy opening. If a pharmacy, licensed as a general, hospital, or limited use pharmacy, opens for business within 10 miles of an existing and operating telepharmacy site, the telepharmacy site may continue to operate as a telepharmacy site and shall not be required to close due to the proximity of the new pharmacy.

657—13.19 to 13.20 Reserved.

657—13.21(124,155A) Policies and procedures. In addition to policies and procedures required for the specific services provided and identified in other chapters of board rules, both the managing pharmacy and the telepharmacy site shall develop, implement, and adhere to written policies and procedures for the operation and management of the specific pharmacy's operations. Policies and procedures shall be available for inspection and copying by the board or the board's representative at the location to which the policies and procedures apply. Policies and procedures shall define the frequency of review and written documentation of review by the pharmacist in charge shall be maintained. Policies and procedures shall address, at a minimum, the following:

- Procedures ensuring a record is made and retained identifying the pharmacist who verified the accuracy of the prescription including the accuracy of the data entry, the selection of the correct drug, the accuracy of the label affixed to the prescription container, and the appropriateness of the prescription container.
- Procedures ensuring a record is made and retained identifying the pharmacist who

performed the drug utilization review as provided by rule 657—8.21(155A).

- Procedures ensuring a record is made and retained identifying the pharmacist who provided counseling to the patient or the patient's caregiver pursuant to rule 657—6.14(155A).
- Procedures ensuring a record is made and retained identifying the technician who filled the prescription.
- Procedures ensuring adequate security to prevent unauthorized access to prescription drugs and devices and to confidential records.
- Procedures regarding procurement of drugs and devices, including who is authorized to order or receive drugs and devices, from whom drugs and devices may be ordered and received, and the required method for documentation of the receipt of drugs and devices.
- Procedures ensuring appropriate and safe storage of drugs at the telepharmacy site including appropriate temperature controls.
- Procedures identifying the elements of a monthly inspection of the telepharmacy site by the pharmacist in charge or designated pharmacist including requirements for documentation and retention of the results of each inspection.
- Procedures for the temporary quarantine of out-of-date and adulterated drugs from dispensing stock and the subsequent documented disposal of those drugs.
- Procedures and documentation required in the case of return to the telepharmacy of a drug or device.
- Procedures for drug and device recalls.

657—13.22(155A) Reports to the board. The board may periodically request information

regarding the services provided by a telepharmacy site. A telepharmacy site shall complete and submit the requested information in a timely manner as requested by the board. The board shall allow a reasonable amount of time for a telepharmacy site to complete and submit the requested information. Information requested may include, but may not necessarily be limited to, the following:

13.22(1) Prescriptions dispensed. The number of prescriptions dispensed from the telepharmacy site over a specified period of time.

13.22(2) Pharmacist hours. The number of hours a pharmacist was physically present at the telepharmacy site over a specified period of time.

13.22(3) Telepharmacy site hours. The number of hours the telepharmacy site was open for business over a specified period of time.

657—13.23(124,155A) Records. Every inventory or other record required to be kept under Iowa Code chapters 124 and 155A or rules of the board shall be kept by the telepharmacy site and be available for inspection and copying by the board or its representative for at least two years from the date of the inventory or record except as specifically identified by law or rule. Controlled substances records shall be maintained in a readily retrievable manner in accordance with federal requirements and 657—Chapter 10. Specific records required to be maintained by and available at a telepharmacy site shall include but are not limited to the following:

13.23(1) Dispensing record. As provided in rule 657—13.21(124,155A), a written or electronic record identifying the pharmacist who verified the prescription, the pharmacist who provided counseling to the patient or the patient's caregiver, and the pharmacy technician who filled the prescription shall be maintained for every prescription fill dispensed by the

telepharmacy site.

13.23(2) Onsite pharmacist staffing. A written or electronic record of the number of prescriptions filled, the number of onsite pharmacist hours, and the number of hours the telepharmacy site was open for business each month.

13.23(3) Pharmacy access. Records identifying, by unique identification of the individual accessing the pharmacy department including the date and time of access, shall be maintained for two years beyond the date of access.

13.23(4) Monthly inspection. Reports of the monthly inspection of the telepharmacy site shall be maintained at the telepharmacy site for two years following the date of the inspection. A copy of the inspection report shall be provided to and maintained at the managing pharmacy for two years following the date of the inspection.

These rules are intended to implement Iowa Code sections 124.301, 147.107, 155A.3, 155A.6A, 155A.13, 155A.14, 155A.19, 155A.28, 155A.31, 155A.33, and 155A.41.